Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2014-015

TO: **ALL DRUG ESTABLISHMENTS AND OUTLETS, AND OTHER STAKEHOLDERS**

FROM: **KENNETH Y. HARTIGAN-GO, MD**
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SUBJECT: **MANUFACTURE, SALE, AND DISTRIBUTION OF TRADITIONAL AND ALTERNATIVE MEDICINES**

The Food and Drug Administration (FDA) has observed continued violations of drug establishments and outlets with regard to the manufacture, sale, and distribution of traditional and alternative medicines in the Philippines.

The Department of Health (DOH), in its efforts to support the integration of traditional and alternative medicines into the national health care system, supported the enactment of Republic Act No. 8432 or the "Traditional and Alternative Medicine Act (TAMA) of 1997".

Under TAMA, traditional and alternative healthcare is defined as "the sum total of knowledge, skills and practices on health care, other than those embodied in biomedicine, used in the prevention, diagnosis and elimination of physical or mental disorder." Consequently, these healthcare systems more or less require the use of drugs recognized in their respective practice; drugs which, by law, are subject to registration.

Consistent with the mandates provided to FDA by Republic Act 9711 also known as "Food and Drug Administration (FDA) Act of 2009", and Republic Act 3720 also known as the "Food, Drug and Cosmetic Act" as amended, as well as the provisions of Republic Act 9502 also known as "Universally Accessible Cheaper and Quality Medicines Act of 2008", the FDA hereby reiterates that **establishments involved in the manufacture, importation, exportation, sale, offer for sale, and distribution of all drug products, including the following are required to be licensed with FDA: (1) allopathic, (2) traditional/alternative (e.g. traditional Chinese medicines, Ayurvedic medicines, homeopathic medicines), and (3) herbal medicines.** Furthermore, **all drug products are required to be registered before they can be marketed, distributed or sold.**

FDA is currently in the process of drafting specific regulations for the registration of these traditional and alternative medicines. However, to assure the public that only safe, efficacious, and quality drugs are available in the market, in the absence of a more specific regulation, these drugs must comply with existing requirements, depending on their classification:

1) For drug products classified as prescription products:
   Administrative Order No. 2013-0021, "Adoption of the Association of Southeast Asian Nations (ASEAN) Common Technical Dossier (ACTD) and Common Technical Requirements (ACTR) for the registration of Pharmaceutical Products for Human Use"

2) For drug products classified as Over-the-Counter (OTC) and Household Remedy (HR):
   Administrative Order No. 67 s. 1989, "Revised Rules and Regulations on Registration of Pharmaceutical Products" and Bureau Circular No,. 05 s. 1997, "Revised Checklist of Requirements and the 1997 Guidelines for the registration of Pharmaceutical Products"

3) For herbal drug products containing plants as active ingredients:
   Administrative Order No. 172 s. 2004, "Guidelines on the Registration of Herbal Medicines"

4) For drug products that are traditionally-used containing plants as active ingredients:
   Administrative Order No. 184 s. 2004, "Guidelines on the Registration of Traditionally-Used Herbal Products"

Any violation from this FDA Circular shall be a ground for filing of appropriate administrative charges and/or imposition of administrative sanctions such as, but not limited to, imposition of fines, suspension, cancellation, or revocation of existing License-to-Operate of drug outlets and establishments, and other legal actions as appropriate.

For your information and compliance.